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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,860	02/18/2005	Takeshi Koizumi	Q86151	2817

23373 7590 11/14/2007  
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WASHINGTON, DC 20037

EXAMINER
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WOOLWINE, SAMUEL C

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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11/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/524,860	Applicant(s) KOIZUMI ET AL.	
	Examiner Samuel Woolwine	Art Unit 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-36, 41, 42, 45-47 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-40, 43, 44, 48 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/5/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status*

Applicant's reply filed 8/30/2007 is acknowledged. Claims 1-50 are pending in the application, of which claims 1-36, 41, 42, 45-47 and 49 have been withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/09/2007.

The rejection of claims 37-40, 43, 44, 48 and 50 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph made in OA 05/30/2007 is withdrawn in view of Applicant's amendment.

With regard to claims 39, 40, 43 and 50, which were also regarded as vague and indefinite based on the limitation "wherein a region that contains, at a high frequency, a position(s) unique to *Vibrio vulnificus* as specified in claim 38 is used", the rejection is maintained for the reasons of record and reiterated below.

The rejection of claims 37-40, 43, 44, 48 and 50 under 35 U.S.C. 112, 1<sup>st</sup> paragraph made in OA 05/30/2007 is maintained for the reasons already of record and reiterated below. Applicant's arguments are addressed following the rejection.

The rejection of claims 37-40, 43, 44, 48 and 50 under 35 U.S.C. 102(b) made in OA 05/30/2007 is maintained for the reasons of record and reiterated below. Applicant's arguments are addressed following the rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 40, 43 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39, 40, 43 and 50 are vague and indefinite because claim 39 recites the limitation "wherein a region that contains, at a high frequency, a position(s) unique to *Vibrio vulnificus* as specified in claim 38 is used". The instant specification was searched for the term "frequency". Other than the claims, this term only appears in the following text: "a gene that is transmitted horizontally at a high frequency" (paragraph [0009] of the published application). The public would have no idea what Applicant considers to be "a high frequency", and therefore the metes and bounds of claim 39 are unclear. Because claims 40, 43 and 50 depend from claim 39, these claims are also vague and indefinite. It is also noted that the limitation "wherein a region that contains, at a high frequency, a position(s) unique to *Vibrio vulnificus* as specified in claim 38 is used" is a recitation of intended use and therefore carries no patentable weight. For purposes of further examination, this limitation will not be considered to distinguish over any prior art that teaches the *structure* of the claimed primer.

### ***Response to Arguments***

Applicant's arguments filed 8/30/2007 have been fully considered but they are not persuasive. Applicant has made no amendments to these claims, nor presented any argument addressing this issue. Therefore the rejection is maintained.

### ***Claim Rejections - 35 USC § 112—Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-40, 43, 44, 48 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For claim 37, the problem stems from the manner in which the claim is written: "A fragment of a polynucleotide having a sequence of SEQ ID NO: 3" is met by any polynucleotide having a *sequence* of SEQ ID NO:3 (even a two nucleotide segment of SEQ ID NO:3. With regard to the limitation "wherein the fragment comprises two or more nucleotides at any of positions 9, 81, 138...", claim 37 is met by any nucleic acid sequence containing two or more nucleotides found at the recited positions in SEQ ID NO: 3 (for example, a "T" residue, which is found at position 153 of SEQ ID NO: 3). In other words, any polynucleotide that contains as little as a two nucleotide sequence found within SEQ ID NO:3, and in addition contains two nucleotides found at the recited positions of SEQ ID NO:3, falls within the scope of the claim. As an illustration, consider the following sequence, typed at random by the examiner:

CCGTATAGTACCTCGAAATCGGTTGCGATTAGAACCA

This sequence has a *sequence* of SEQ ID NO:3. As seen in SEQ ID NO:3 below, the sequence CC occurs at the beginning. This sequence of SEQ ID NO:3 is found in the random sequence above. Also, the random sequence above comprises all

four of the natural nucleotides, and therefore also comprises two or more nucleotides found at the recited positions of SEQ ID NO:3.

```
<210> SEQ ID NO 3
<211> LENGTH: 648
<212> TYPE: DNA
<213> ORGANISM: Artificial Sequence
<220> FEATURE:
<223> OTHER INFORMATION: Description of Artificial Sequence: consensus sequence of the
      recA gene of the cluster to which Vibrio vulnificus belongs
<220> FEATURE:
<221> NAME/KEY: misc_feature
<222> LOCATION: (330)..(330)
<223> OTHER INFORMATION: n is a, c, g, or t
<400> SEQUENCE: 3
      ccaatgggcc gtatcgttga aetttttggg ccagaatctt caggtaaaac cacgttgacc      60
      cttgagctga tcgctgcrgc tcaacgtgaa ggcaaaactt gtgcgtttat cgatgcygag      120
      cecgcgttrg atcctgtgta tgcgaagaar cttggcggtwa atatcgacca rtttttggtgta      180
      tctcagccyg ayachgggtga acaagcrttg gaaatctgtg atgckcttgc tcgctcaggk      240
      gccgttgayg ttattgttgt cgaytctgtk gcmgcattga crccaaaggc agaaatygaa      300
      ggtgagatgg gygaytcgca catgggtctn caagctcgtg tgctmtctca agcgatgcgt      360
      aegytaacgg gkeacctaana rcagtctaac tgtatgtgta tcttccatyaa ccagatycgt      420
      atgaagatyg gkgtgatgtt tggtaeycca gaaccacaaa crggtggtaa cgcwctgaaa      480
      ttctacgctt ctgtwcgtct tgatattcgc cgtactgggt cratcaaaga aggygatgag      540
      gtmgtgggta aygaaacgcy yatcaaagtg gtgaagaata agatcgctgc gccgtttaaa      600
      geagccaaya cycaaattat gtaayggccar ggcwtttaacc gygaaggy      648
```

A similar interpretation can be made for claims 38 and 48, which require only that the claimed primer/probe comprises at least 15 nucleotides, and comprises two or more nucleotides found at the recited positions of SEQ ID NO: 3. Therefore, the claims define an incredibly broad genus of possible polynucleotides. As all claims depend from either claim 37, 38, or 48, all claims are likewise rejected under this section.

As stated in MPEP 2163 (II)(A)(3)(a)(ii), the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying

characteristics, sufficient to show the applicant was in possession of the claimed genus.

Reduction to practice:

The sequence of SEQ ID NO: 3 is disclosed, as are the sequences of SEQ ID NOS: 17-20 which are apparently derived from SEQ ID NO: 3. However, as noted above, the claims as currently written encompass a genus far beyond the disclosure of SEQ ID NO: 3. The claims read, for example, on gene fragments from genes encoding the RecA homologs from other species (since these homologous genes undoubtedly contain one or more nucleotides that are found at the recited positions of SEQ ID NO: 3). There is no written description of such homologous genes. Indeed, the claims as written structurally require, at most, a polynucleotide of at least 15 nucleotides, which contain a nucleotide found at one of the recited positions in SEQ ID NO: 3, and which could be used as a primer or probe for detecting *Vibrio vulnificus* (claims 38-40, 43, 44 and 48) or could be used to design such a primer or probe (claims 37, 50). In other words, the claims are not limited to the sequences within the disclosed SEQ ID NO: 3.

Reduction to drawings:

There is a drawing (figure 4) depicting a sequence for recA, presumably the same as SEQ ID NO: 3.

Relevant identifying characteristics:

Applicant has disclosed the sequence of SEQ ID NO: 3, but has not identified relevant identifying characteristics of the genus encompassing any polynucleotide greater than 15 nucleotides in length, containing a nucleotide found at recited positions of SEQ ID NO: 3, that could be used as a primer or probe, or used to design a primer or

probe, for quantifying, detecting or identifying *Vibrio vulnificus*. It seems that Applicant is attempting to claim fragments of the sequence of SEQ ID NO: 3 that encompass certain positions of the sequence. Applicant is advised to amend the claims so that broader claim interpretations, which result in an unintentionally large and undescribed genus, do not apply.

### ***Response to Arguments***

Applicant's arguments filed 8/30/2007 have been fully considered but are not persuasive. Applicant relies solely on the amendment to the claims to overcome the rejection (section III, page 13 of the response). The amendment does not overcome the rejection, because the claim is written in such a way as to encompass a very large and undescribed genus, as discussed in the rejection above.

Applicant may wish to consider an amendment that requires the claimed polynucleotide to comprise a sequence of some number of contiguous nucleotides found within SEQ ID NO:3, which encompasses two or more of the positions recited in the claims. For example, "a polynucleotide comprising a sequence of 15 contiguous nucleotides found within the sequence of SEQ ID NO:3, wherein said sequence comprises positions 138 through 153 of SEQ ID NO:3". This language defines a core structure which, as discussed in the rejection above, discloses the relevant, identifying characteristics of the genus.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:



A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-40, 44 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank® GI:16565115, 1-Nov-2001, [online], [retrieved on 5/22/2007], retrieved from the Internet: <URL: [www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?16565115:OLD12:801996](http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?16565115:OLD12:801996)>.

37. (currently amended): A gene fragment ~~represented by of a polynucleotide having a nucleotide sequence of SEQ ID NO: 3, wherein the fragment comprises which contains one or more nucleotides at any of two or more nucleotides at any of positions 9, 81, 138, 153, 172, 180, 208, 228, 237, 288, and 540 in a gene (*recA*) encoding RecA of SEQ ID NO: 3 in the sequence listing, said positions being unique to the *Vibrio vulnificus* bacterial group, where said gene fragment can be used for designing a specific gene amplification primer or a specific probe.~~

With regard to claim 37, GenBank® GI:16565115 discloses a nucleotide sequence of 543 nucleotides that is a “fragment of a polynucleotide having a nucleotide sequence of SEQ ID NO: 3”. An alignment of SEQ ID NO: 3 with GenBank® GI:16565115 is shown below. It is noted that GenBank® GI:16565115 positions 238-258 correspond exactly to positions 133-153 of SEQ ID NO: 3 (and thus also the elected species of SEQ ID NO: 17). This particular region is underscored in the alignment below. GenBank® GI:16565115 is from *Vibrio vulnificus* and can be used for designing a specific gene amplification primer or a specific probe (in fact this sequence could itself serve as a specific gene amplification primer or a specific probe).

With regard to claim 38, GenBank® GI:16565115 contains at least 15 continuous nucleotides, including nucleotides found at positions 133-153 of SEQ ID NO: 3, and can be used as a gene amplification primer.

With regard to claim 39, the limitation “wherein a region that contains, at a high frequency, a position(s) unique to *Vibrio vulnificus* as specified in claim 38 is used” is a recitation of intended use that does not structurally distinguish over the primer disclosed by GenBank® GI:16565115.

With regard to claim 40, GenBank® GI:16565115 contains at least 15 continuous nucleotides, including nucleotides found at positions 133-153 of SEQ ID NO: 3, and can be used as a gene amplification primer.

With regard to claim 44, GenBank® GI:16565115 positions 238-258 correspond exactly to positions 133-153 of SEQ ID NO: 3 (and thus also the elected species of SEQ ID NO: 17). This particular region is underscored in the alignment below. The entire sequence of GenBank® GI:16565115 can be used as a gene amplification primer, and it “contains” SEQ ID NO: 17.

With regard to claim 48, as discussed above, GenBank® GI:16565115 positions 238-258 correspond exactly to positions 133-153 of SEQ ID NO: 3. GenBank® GI:16565115 also contains 15 or more continuous nucleotides and can be used as a probe for detecting, quantifying or identifying *Vibrio vulnificus*.

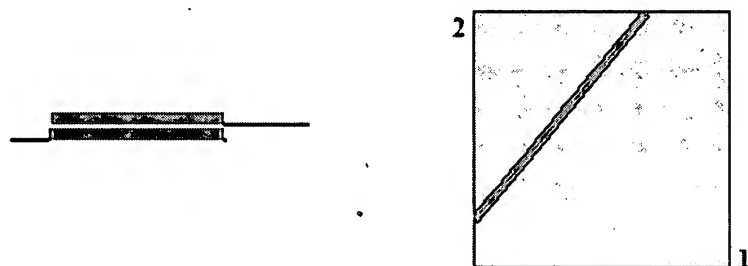
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Sequence 1: lc|SEQID NO 3

Length = 648 (1 .. 648)

Sequence 2: gj|16565115|gb|AF311535.1|Vibrio vulnificus strain 9067-96 recombinaase A (recA) gene, partial cds.

Length = 543 (1 .. 543)



NOTE: Bitscore and expect value are calculated based on the size of the nr database.

NOTE: If protein translation is reversed, please repeat the search with reverse strand of the query sequence.



Score = 797 bits (402), Expect = 0.0  
Identities = 404/434 (93%), Gaps = 0/434 (0%)  
Strand=Plus/Plus

```
Query 1 CCAATGGGCCGTATCGTTGAAATTTTGGTCCAGAATCTTCAGGTAAAACCACGTTGACC 60
      |||
Sbjct 106 CCAATGGGCCGTATCGTTGAAATTTTGGTCCAGAATCTTCAGGTAAAACCACGTTGACC 165

Query 61 CTGAGCTGATCGCTGCRGCTCAACGTGAAGGCAAACTTGTGCGTTTATCGATGCGYAG 120
      |||
Sbjct 166 CTGAGCTGATCGCTGCGGCTCAACGTGAAGGCAAACTTGTGCGTTTATCGATGCCGAG 225

Query 121 CACGCGTTTGATCCTGTGTATGCGAAGAARCTTGGCGTWAATATCGACCARTTRITGGTA 180
      |||
Sbjct 226 CACGCGTTTGATCCTGTGTATGCGAAGAARCTTGGCGTTAATATCGACCAGTTGTTGGTA 285

Query 181 TCTCAGCCYGAYACBGGTGAACAAGCRITGGAAATCTGTGATGCKCTTGCTCGCTCAGGK 240
      |||
Sbjct 286 TCTCAGCCCGACACCGGTGAACAAGCATTGGAAATCTGTGATGCTCTTGCTCGCTCAGGT 345

Query 241 GCGGTTGAYGTTATTGTTGTCTGAYTCTGKCGMGCATTGACRCCAAAGGCAGAAATYGAA 300
      |||
Sbjct 346 GCGGTTGACGTTATTGTTGTCTGACTCTGTTGACGATTGACACCAAGGCAGAAATCGAA 405

Query 301 GGTGAGATGGGYGAYTCGCACATGGGTCTNCAAGCTCGTATGCTMTCTCAAGCGATGCGT 360
      |||
Sbjct 406 GGTGAGATGGGCGACTCGCACATGGGTCTTCAAGCTCGTATGCTATCTCAAGCGATGCGT 465

Query 361 AAGYTAACGGGKAACCTAAARCAGTCTAACTGTATGTGTATCTTCATYAACCAGATYCGT 420
      |||
Sbjct 466 AAGTTAACGGGTAACCTAAAGCAGTCTAACTGTATGTGTATCTTCATCAACCAGATCCGT 525

Query 421 ATGAAGATYGGKGT 434
      |||
Sbjct 526 ATGAAGATTGGTGT 539
```

### ***Response to Arguments***

Applicant's arguments filed 8/30/2007 have been fully considered but are not persuasive. Applicant relies solely on the amendment to the claims to overcome the rejection (section IV, page 13 of the response). The amendment does not overcome the rejection, as discussed in the rejection above.

Claims 37-40, 43, 44, 48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Random Primer 24, sold by New England Biolabs (see page 121 of the 1998/99 New England Biolabs Catalog; this reference was cited and supplied in a previous Office action).

Random Primer 24 contains every possible 24-nucleotide sequence. The following calculations rely on facts provided on page 284 of the catalog, specifically the mass of 1.0 A<sub>260</sub> unit of single-stranded DNA and the molecular weight of single-stranded DNA per nucleotide (i.e. half the weight of a double-stranded DNA per basepair):

Random 24-mer:

Molecular weight of 24-mer:

$$24 \times 325 \text{ daltons/nucleotide} = 7,800 \text{ daltons} = 7,800 \text{ g/mol}$$

Number of possible 24-mers:

$$4^{24} = 2.8 \times 10^{14} \text{ molecules}$$

How many molecules of 24-mer in a vial sold by NEB:

$$1 \text{ A}_{260} \text{ unit} = 33 \text{ } \mu\text{g} = 3.3 \times 10^{-5} \text{ g}$$

$$3.3 \times 10^{-5} \text{ g} \div 7,800 \text{ g/mol} = 4.2 \times 10^{-9} \text{ mol}$$

$$(4.2 \times 10^{-9} \text{ mol}) \times (6.02 \times 10^{23} \text{ molecules/mol}) = 2.5 \times 10^{15} \text{ molecules}$$

How many vials needed to sum to 1 of each possible 24-mer:

$$2.8 \times 10^{14} \text{ molecules} \div 2.5 \times 10^{15} \text{ molecules} = 0.11 \text{ vial}$$

Put another way, every vial of Random Primer 24 sold by New England Biolabs would be expected to contain 9 copies of every possible 24-nucleotide sequence. Therefore, Random Primer 24 would contain every possible gene fragment imaginable that is 24 nucleotides in length, thus meeting the limitations of claims 37-40, 43, 44 and 48, including the limitation of "at least 15 continuous nucleotides" recited in claims 38 and 48. Furthermore, with regard to claim 50, Random Primer 24 is itself a kit (it was a commercially sold product at least as early as 1998). It could also be used for detecting, quantifying or identifying *Vibrio vulnificus*. For example, it could be used to make a labeled probe by random priming using a *Vibrio vulnificus* template nucleic acid.

### ***Response to Arguments***

Applicant's arguments filed 8/30/2007 have been fully considered but are not persuasive. Applicant relies on the amendment to the claims to overcome the rejection (section IV, page 13 of the response). The amendment does not overcome the rejection, as discussed in the rejection above.

Applicant also argues that the NEB catalog does not disclose fragments having a nucleotide sequence of SEQ ID NO:3. This argument is not persuasive. As stated at MPEP 2112:

"The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of

anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983)."

Here, the examiner is relying on the inherent disclosure of the prior art reference. The reference evidences that a prior art product was sold as early as 1998, and that this product, because it contained all possible 24 nucleotide sequences, inherently contained nucleotide sequences meeting the limitations of the claims.

Applicant further argues that, because the examiner's calculations were based on the average molecular weight of a DNA base pair, the results of the calculations are unreliable. This is not persuasive; the use of an average value is a perfectly acceptable practice in such calculations, particularly when there are only 4 possibilities of known molecular weight.

Applicant argues that, just because Rothstein et al used the NEB product to detect a 123 bp fragment, this does not mean the NEB product contained polynucleotide fragments meeting the limitations of the claims. This argument is not persuasive. The examiner has presented a *prima facie* case for inherent anticipation. If Applicant wishes to submit evidence, such as failed attempts to synthesize a labeled probe using the NEB product with SEQ ID NO:3 as a template, such evidence would be more persuasive. Note that the claims only require a polynucleotide having a *sequence* of SEQ ID NO:3 (even a two nucleotide sequence) and that the polynucleotide comprise

two or more of those nucleotides found at the recited positions of SEQ ID NO:3 (see rejection under 35 U.S.C. 112, 1<sup>st</sup> paragraph, above).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

scw

/Young J. Kim/  
Primary Examiner  
Art Unit 1637  
Technology Center 1600